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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/645,078	08/23/2000	Annette Bistrup	06510-107CIP2	2678

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EXAMINER	
MORAN, MARJORIE A	

ART UNIT	PAPER NUMBER
1631	10

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application N .	Applicant(s)	
	09/645,078	BISTRUP ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-38* is/are pending in the application.

4a) Of the above claim(s) *4-15* is/are withdrawn from consideration.

5)☒ Claim(s) *1 and 16-20* is/are allowed.

6)☒ Claim(s) *21-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *9* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Applicant's affirmation of the election with traverse of Group I, claims 1-3, in Paper No. 8 is acknowledged. The traversal is on the ground(s) that a search for the all of the Groups would not be unduly burdensome. This is not found persuasive because a search for any single Group requires a search of nonpatent literature and foreign patents as well as US patents. In addition, the polypeptides of the instant claims can be used in a variety of methods, as set forth in the previous office action. A search for any single product or structure (e.g. antibody or animal) is necessarily a different search than that for any other product. For these reasons, the examiner maintains that a search for all Groups would be unduly burdensome and maintains that the restriction is proper. Arguments with regard to rejoinder of method claims will be held in abeyance until product claims are found to be allowable. It is noted that at least some claims directed to methods of use of the protein recited in claim 1 have been issued in US Patent 6,365,365. It is further noted that methods of producing a protein encoded by a sequence identical to instant SEQ ID NO: 1 are currently pending in related application 09/816,825.

The requirement is still deemed proper and is therefore made FINAL.

Priority

Applicant claims priority to a series of applications with filing dates of 2/26/1999, 11/12/1998, and 3/20/1998. Support for SEQ ID NO's 1 and 2 can be found in at least 09/190,911 (now US 6,365,365) filed 11/12/1998 and 09/045,284 (now US 6,265,192)

filed 3/20/1998, therefore claims reciting ONLY these SEQ ID NO's are granted priority to the earliest filing date of 3/20/1998. No support for SEQ ID NO: 3 or SEQ ID NO: 4 can be found in any of the applications for which priority is claimed, therefore priority for claims reciting either of these SEQ ID NO's is granted only to the filing date of the instant application, of 8/23/2000. For these reasons, claims 1, 3, 16-20, and 34-37 are granted a priority date of 3/20/1998. Claims 21-33 and 38 are granted a priority date of 8/23/2000.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 31-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

A fragment of a nucleotide sequence with at least 75% identity to SEQ ID NO: 1 (i.e. a GST-3 polypeptide) which catalyzes the transfer of a sulfate group from a donor to a selectin ligand is new matter. In the response filed 6/11/03, applicant points to page 8 for support for the newly added limitations of claim 3. Page 8 of the originally filed specification does provide support for mammalian GST-3 proteins which catalyze

transfer of a sulfate group from a donor to a selectin ligand, in lines 13-22. Pages 8-9 of the specification also describes human and mouse GST-3 polypeptides by number of amino acids and molecular weight. Pages 8-9 of the specification do not, anywhere, disclose FRAGMENTS of a GST-3 polypeptide which catalyze sulfate transfer. Pages 10 and 12 of the specification disclose that embodiments of applicant's invention include fragments of particular sizes, wherein the fragments may correspond to "functional domains". Page 10 does not, however, define a "biologically active fragment" or one which corresponds to a "functional domain" to be a fragment with catalytic activity. Page also discloses that domains may correspond to a donor binding site and acceptor binding site, but does not disclose specific fragments comprising these sites, nor does the specification disclose that binding sites are necessarily catalytic domains. Page 45 of the specification discloses regions of "identity" shared between members of the family of sulfotransferases and specifically identifies highly conserved residues thought to contribute to binding of a sulfate donor and/or acceptor. This is not, however, a disclosure that any of the disclosed "regions" or conserved amino acids are actually catalytic. It is well known in the enzyme art that while a catalytic domain MAY comprise one or more binding regions, a binding region, per se, is not necessarily the same as the catalytic domain of an enzyme. Further, it is well known in the art that a binding region, per se, is not generally catalytic; i.e. the residues which bind a ligand are not usually those involved in cleavage and subsequent transfer of a molecule such as sulfate. For these reasons, mere disclosure of a domain PSOTULATED to be involved in binding an acceptor molecule is not support for fragment "which catalyzes

transfer....". Similarly, disclosure of conserved residues in a donor binding site is not a disclosure that those residues (or the donor binding site) are a fragment "which catalyzes transfer..." Pages 47-48 of the originally filed specification exemplify methods of measuring/detecting sulfate transfer, and specifically sulfation of a selectin ligand. The examples do not disclose that any "fragments" of a GST-3 polypeptide were used. The specification does not specifically identify, anywhere, a fragment or fragments of a GST-3 polypeptide known to comprise catalytic sulfate transfer activity. The originally filed claims did not recite fragments of a GST-3 polypeptide, specifically SEQ ID NO: 1, comprising catalytic activity. As neither the originally field specification or claims provide support for the newly recited limitations of claim 3, claims 3 and 31-37 recite new matter.

Claim 32 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a LACK OF WRITTEN DESCRIPTION rejection.

A functional domain which is an acceptor binding site on a GST-3 peptide, specifically SEQ ID NO: 1 is not fully and completely described anywhere in the specification. Page 10 of the instant specification discloses that embodiments of the invention include functional domains such as an acceptor binding site, "postulated to be

the 5' most consensus region A". Page 45 discloses that consensus regions 1 and 3 contain two stretches of conserved amino acids which are SUGGESTED to contribute to a binding pocket which interacts with a sulfate acceptor. The specification does not disclose that any of the consensus regions disclosed are known or were found to actually bind a sulfate acceptor compound. My contract, the specification discloses a specific sequence, on page 10, known to bind sulfate donors, and discloses that consensus binding motifs for sulfate donors are known in the art and are found in all sulfotransferases to date. Similar art-recognized sequences or binding motifs for sulfate acceptor compounds are not disclosed in the instant specification. As the specification does not provide a full and complete description of fragment of SEQ ID NO: 1 which comprises a "functional domain" which is an acceptor binding site, claim 32 is rejected for lack of written description.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 21 is rejected under 35 U.S.C. 102(a) as being anticipated by TANG et al. (WO 00/14251).

TANG teaches a transferase polypeptide identified as SEQ ID NO: 11 which is 70.9% identical to instant SEQ ID NO: 4 (Sequence page 13), thereby anticipating claim 21.

Claims 21-24, 26, 28-30, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by HIROAKA et al. (Immunity (July, 1999) vol. 11, no. 1, pp. 79-89).

HIROAKA teaches an LSST polypeptide which is 99.6% identical to SEQ I DNO: 4, and which is encoded by a polynucleotide sequence 98.9% identical to SEQ ID NO: 3 (p. 81, Figure 2), thus anticipating claims 21-24 and 38. HIROAKA discloses that ligands for his LSST include GlyCAM-1, CD34, and MadCAM-1 (abstract), and that his LSST may also be involved in sulfation of P-selectins (p. 86), thus anticipating claims 26 and 28-30.

Claims 21-30 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by BISTRUP et al. (Journal of Cell Biol. (May 17, 1999) vol. 145, no. 4, pp. 899-910).

BISTRUP teaches a polypeptide which is 100% identical to SEQ ID NO: 4, and which is encoded by a polynucleotide 100% identical to SEQ ID NO: 3 (p. 904, Figure 3), thus anticipating claims 21-25 and 38. A property is inherent to a structure/sequence. As the polypeptide taught by BISTRUP is identical to that claimed, all properties recited in the claims (i.e. sulfation of specific ligands) are inherent, and claims 26-30 are also anticipated.

Allowable Subject Matter

Claims 1 and 16-20 are allowed over the prior art.

Conclusion

Claims 1 and 16-20 are allowed; claims 3 and 21-38 are rejected. Claims 4-15 are again withdrawn.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

MARJORIE MORAN
PATENT EXAMINER

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